MICHIGAN RHEUMATISM SOCIETY

October 13, 2015

The Honorable Mike Callton
Chairman, House Health Policy Committee
Anderson House Office Building,
P.O. Box 30014, Lansing, MI 48909

Re: Support House Bill 4812 (Bizon)

Dear Representative Callton and Members of the Health Policy Committee:

On behalf of the Michigan Rheumatism Society (MRS) and our physician members, I am writing in support of HB 4812. We believe this legislation is a common sense solution to ensuring patient safety and transparency by requiring communication to the prescribing physician when substituting a biological product with an interchangeable biologic drug.

Biologic medications have offered breakthroughs in the treatment of rheumatic diseases. These medications attack the symptoms and disease at the source, helping to treat and control a patient's pain.

Biosimilars and interchangeable biologics offer another step in the ability to provide patients affordable, effective care. However, a biosimilar will never be an exact replica of a biologic. Because of this difference between medications, it is imperative that only federal Food and Drug Administration approved interchangeable biologics are allowed to be substituted, and that physicians and patients are made aware of the specific biologic dispensed.

- **MRS supports HB 4812** because it meets the requirements listed above and provides that within five business days of dispensing a biological drug product, the pharmacist must communicate the dispensing information to the prescriber.
- **MRS opposes the adoption of HB 4437**, which goes against FDA recommendations and would allow non-interchangeable drugs to be substituted, despite their differences.

We urge the Health Policy Committee to support HB 4812. We look forward to working with you to make sure this important legislation is adopted to protect Michigan patients.

Sincerely,
Amar Majjhoo, MD

Amar Majjhoo, MD
President, Michigan Rheumatism Society

AfPA National Physicians Biologics Working Group

October 2, 2015

The Honorable Mike Callton
Chairman
House Health Policy Committee
Anderson House Office Building
P.O. Box 30014
Lansing, MI 48909-7514

RE: Support for HB 4812 – FDA-designated interchangeable biological drug products; allow pharmacists to dispense.

Dear Chairman Callton:

On behalf of our Michigan members and their patients, the Alliance for Patient Access (AfPA) would like to express support for HB 4812, allowing for the substitution of biological medicines when certain conditions are met. The legislation as drafted contains the patient safety principles that AfPA member physicians have identified as critical for safe access to biosimilar medications, notably physician communication of substitution, and is worthy of your support.

AfPA is a national network of more than 700 physicians with the shared mission of ensuring and protecting patient access to approved medical treatments and therapies, including prescription pharmaceuticals, biologics, and medical devices. Since 2011, AfPA has convened the National Physicians Biologics Working Group (NPBWG) as a home for physicians interested in policy issues relating to access to biologic therapies.

The NPBWG identified key principles that biosimilar substitution must meet to ensure patient safety and promote prescriber confidence. These include FDA designation of a product as interchangeable before it may be substituted for a prescribed biologic, that pharmacists communicate to the prescribing physician and patient any substitution with in a reasonable timeframe, that physicians be allowed to specify no substitution, and that patients be notified of any substitution. HB 4812 contains these safety provisions, most importantly the physician communication provision that helps ensure a complete medical record and helps assure the best medical response to a patient adverse event. AfPA is pleased that HB 4812 allows for substitution while containing provisions to implement these safeguards.

The Food and Drug Administration (FDA) has already approved one biosimilar medicine and may soon approve interchangeable biosimilar medicines. AfPA supports making potentially less costly medicines available to patients and physicians but all efforts must be made to create policies that balance access, safety and cost. HB 4812 provides this pathway for biosimilar medicines by maintaining communication safeguards and is worthy of your support in its current form.

Sincerely,

Brian Kennedy
Executive Director

Cc: Members, House Health Policy Committee

Alliance for Patient Access
2000 M Street, NW, Suite 850
Washington, D.C. 20036
www.AllianceforPatientAccess.org

Saginaw County
MEDICAL SOCIETY

350 St. Andrews Road Suite 242 Saginaw, MI 48638-5988 (989) 790-3590 Fax (989) 790-3640
Email: jmcramer@sbcglobal.net www.saginawmedicalsociety.org

October 7, 2015

Dear Members of the Health Policy Committee:

As board members of the Saginaw County Medical Society, we are writing in support of HB 4812. We believe this legislation is a common sense solution to ensuring patient safety and transparency by requiring physician notification when substituting a biological product with a biosimilar.

Biosimilars offer a step forward in the ability to provide patients affordable, effective care. However, a biosimilar will never be an exact replica of a biologic. Because this difference between medications exists, doctors must be part of the decision-making process. They should determine when it is in the patient's best interests to substitute a biologic for a biosimilar. Cutting doctors out of this process puts the patient at risk.

Creating a line of communication between the prescriber and the dispenser protects patients and ensures the doctor has the correct information to determine treatments. We support HB 4812 because it requires that within five days of dispensing a biological drug product, the pharmacist must share the dispensing information with the prescriber. We do not support HB 4437, which goes against the Federal Food and Drug Administration's recommendations and allows biologics be substituted with biosimilars, despite their differences.

We urge members of the Health Policy Committee to support HB 4812. We look forward to working with you to make sure this important legislation is adopted to protect Michigan patients.

Sincerely,

Danielle C. Duncan, MD

DANIELLE C. DUNCAN, MD
President

Since 1902

October 15, 2015

Chairman Mike Callton
Anderson House Office Building
N-1191 House Office Building
Lansing, MI 48933

Dear Chairman Callton,

As CEO and Executive Director of the Michigan Osteopathic Association (MOA), I am writing on behalf of the over 8,000 osteopathic physicians and medical students in the state of Michigan. MOA seeks to promote quality patient care in the practice of osteopathic medicine and Michigan. With this mission in mind, MOA seeks to express support for HB 4812 and concern for HB 4437 regarding biologic and biosimilar medications.

Biologic medications are complex medications made out of living cells. Biosimilars are made to be similar to their biologic counterpart, however because of their complexity it is impossible to make an exact copy of the originator biologic medication. The Federal Food and Drug Administration (FDA) has created two categories, biosimilars and interchangeable biosimilars.

We believe HB 4812, introduced by Dr. John Bizon, meets the FDA's recommendations and the goals of MOA to provide quality care. This legislation allows for the substitution of only interchangeable biosimilars and requires pharmacists to communicate with doctors after making biologic medication substitutions. It is critical, and commonsense, for doctors to have a complete patient record when making health care decisions.

It is because of this stance that MOA is extremely concerned about possible passage of HB 4437, introduced by Representative Ken Yonker. This bill sets a dangerous precedent by going against the FDA's guidelines for biosimilar substitution. In addition to allowing these irresponsible substitutions, it cuts doctors out of the conversation.

I urge you to pass HB 4812, Michigan patients deserve the highest quality of care.

Sincerely,

Kris Nicholoff
CEO/ Executive Director
Michigan Osteopathic Association

MICHIGAN OSTEOPATHIC ASSOCIATION

2445 WOODLAKE CIRCLE OKEMOS, MI 48864 TOLL FREE 800.657.1556

MICH BIO
DRIVING BIO-INDUSTRY GROWTH

Bio
Biotechnology Industry Organization

STATEMENT IN OPPOSITION TO MICHIGAN HOUSE BILL 4437

submitted by

Stephen Rapundalo, PhD
President and CEO, MichBio

Position: The Michigan Biosciences Industry Association (MichBio) and Biotechnology Industry Organization (BIO) opposes Michigan House Bill 4437 which would amend the law in Michigan to conflict with changes to federal law that created an abbreviated pathway for FDA approval of biosimilar drug products. HB 4437 does NOT sufficiently protect patients when recognizing the unique attributes of biosimilar drug products. The proposed legislation:

1. **Allows substitution with a biosimilar NOT approved by the FDA as interchangeable;**
2. **Does NOT require the pharmacy to communicate with the prescriber after an interchangeable biosimilar is dispensed and thereby preserve a complete health record;**
3. **Does NOT aid post-market surveillance/adverse event reporting processes for good public health practice and efficient patient care;**
4. **Does NOT safeguard primacy of the physician-patient relationship;**
5. **Is NOT consistent with biologic substitution legislation already adopted in 18 other states;**
6. **Does NOT put the patient's interests first;**
7. **Is NOT supported by patient and provider groups.**

Chairman Callton and members of the committee - thank you for the opportunity to speak before you on House Bill 4437, a bill concerning the substitution of biologic medicines.

My name is Dr. Stephen Rapundalo. I am President and CEO of MichBio, the Michigan Biosciences Industry Association. Our Association and the national Biotechnology Industry Organization (BIO) of which MichBio is a state affiliate represent the biotechnology and pharmaceutical companies developing biologic medicines for curing and treating many of the most complex and life threatening diseases.

By background, I am a protein and molecular biologist, biochemist and pharmacologist by training. Prior to MichBio I spent almost 20 years in drug discovery developing new therapies for cardiovascular disease, everything from small molecule drugs, most notably Lipitor, to biologics. I've been part of several FDA new drug applications and review processes. At MichBio I'm involved routinely with the FDA on regulatory policy and with Congress on legislative policy governing drug and medtech product development.

Today I'd like to set the record straight on various aspects of HB 4437 and convince you that the legislation is not in the best interests of patients and responsible healthcare delivery.

HB 4437 Does <u>NOT</u> Fully Support Patients; Inconsistent with Federal 21st Century Cures Act.

Let's begin with the assertion made at last week's hearing that HB 4437 is consistent with the federal 21st Century Cure Act passed by the U.S. House through the leadership efforts of Rep. Fred Upton. It's true that 21st Century Cures is about accelerating drug and device development. However, its greatest significance is that it is patient-centric. Patients were

engaged throughout the development of the legislation and its key elements reflect patient interests. HB 4437 does not put the patient first.

HB 4437 Is NOT Consistent with FDA Guidance on Biologics and Biosimilars.

Furthermore, and despite assertions made previously, HB 4437 is not consistent with the FDA's guidance on biologics and interchangeable biosimilars. Specifically Sec. 11709 (6) would allow substitution of biosimilars. Doing so would compromise patient safety given the complexity of biologic proteins. It runs contrary to the FDA's policy whereby only clinically-validated biosimilars are allowed to be interchangeable for the innovator biologic. So again, HB 4437 does it put patients first and is not wise from a public health standpoint.

HB 4437 Does NOT Require Pharmacist-Prescriber Communication to Preserve a Complete Patient Health Record.

MichBio and BIO believe that transparency in health care delivery and records is paramount. Open communication between the pharmacist and physician should be a requirement so that the prescriber can make medical decisions based on the exact medication the patient is taking. This is predicated on having a complete and shared patient health record.

The argument that communication would be an added burden to the dispenser is simply a red herring. A lack of technological ability to adequately record and communicate electronically in this age of telemedicine simply reflects an inadequacy on the part of dispensers' operations and a detriment to proper patient healthcare.

Some have argued that the FDA opposes state biosimilar substitution laws and/or does not support prescriber communications provisions. Let's be very clear – the FDA has taken no

formal position in either regard because regulation of medical practices including dispensation of drugs falls within state jurisdiction. It is Michigan's duty to establish regulations and guidelines for the proper use and substitution of interchangeable biosimilars with patients' best interests in mind.

Does NOT aid post-market surveillance/adverse Event Reporting and Efficient Patient Care.

You've heard that there is a heightened risk of adverse immune reactions as biologic medicines are different in the way they interact in the body. Sometimes these occur after a patient has been on the product for a long time. While infrequent, the body may also build up an immune response to the biologic medicine that impacts the efficacy of the medicine.

Thus, any untoward events should be tracked – both for post-market compliance and good public health practice. Pharmacist-prescriber communication is the first step in ensuring that goal is met.

HB 4437 Does NOT Preserve Primacy of Patient-Physician Relationship.

The patient- physician relationship is sacrosanct. An incomplete health record due to the lack of communication by a pharmacist regarding a biosimilar substitution shortchanges proper decision-making over health issues.

HB 4437 and its H-2 Substitution Is NOT the National Model

MichBio and BIO oppose House Bill 4437 as it includes provisions that do not fully recognize the special nature of biologics and biosimilars, runs in conflict with FDA guidelines for the substitution only of interchangeable biologics, and fails to recognize the critical importance of transparency necessary to dispense these special medications and ensure patient safety.

Moreover, the H-2 substitution includes language that is not advocated, supported or implemented anywhere else in the world. In sum, HB 4437 is NOT the national model for biosimilars substitution adopted in 18 other states.

HB 4437 Is NOT Supported by Patient Groups.

Lastly, MichBio and BIO oppose HB 4437 as it isn't patient-centric. Passage of the bill would set a dangerous and irresponsible precedent and place patient safety at risk. It's why patient groups do not support the legislation. Furthermore, our position is not the least bit anti-competitive as our coalition is comprised of not only of patient groups but also innovators, biosimilar and generic manufacturers, benefit managers and prescribers.

That is why we believe that HB 4812 is the better legislation that supports quality care and places the emphasis on the patient first, foremost and always. And that's why HB 4812 reflects the national legislation model.

Thank you for your consideration.